



VACCINE MANAGEMENT

**Recommendations for Handling
and Storage of Selected Biologicals**

January 2001

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DTaP: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine
DTaP/ACTHIB: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine Combined with *Haemophilus Conjugate Vaccine*
DTP: Diphtheria Toxoid, Tetanus Toxoid, Whole Cell Pertussis Vaccine
DTP/HIB: Diphtheria Toxoid, Tetanus Toxoid, Whole Cell Pertussis Vaccine Combined with *Haemophilus Conjugate Vaccine ***

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 2°-8°C (35°-46°F). **Do not freeze** or store vaccine in direct contact with refrigerant.

Condition on Arrival*

Should not have been **frozen**. Refrigerate on arrival.

Storage Requirements

Refrigerate immediately on arrival. Store at 2°-8°C (35°-46°F). **Do not freeze**.

Shelf Life

Up to 18 months. Check date on vial or container.

Instructions for Reconstitution or Use

Shake vial vigorously before withdrawing each dose.

Shelf Life after Reconstitution, or Opening

Until outdated, if not contaminated.

Special Instructions

Rotate stock so that the shortest dated material is used first.

HBIG: Hepatitis B Immune Globulin

Shipping Requirements

Should be shipped in insulated container.

Condition on Arrival*

Should not have been **frozen**. Refrigerate on arrival.

Storage Requirements

Refrigerate immediately on arrival. Store at 2°-8°C (35°-46°F). **Do not freeze**.

Shelf Life

Up to 1 year. Check date on vial or container.

Instructions for Reconstitution or Use

Shake vial vigorously before withdrawing each dose.

Shelf Life after Reconstitution, or Opening

Until outdated, if not contaminated.

Special Instructions

Rotate stock so that the shortest dated material is used first.

* If you have questions about the condition of the material at the time of delivery, you should:

1) Immediately place material in recommended storage; and 2) Notify the Quality Control office of the vaccine manufacturer; or 3) Notify the National Immunization Program, CDC, Atlanta, Georgia.

** ACTHIB – Aventis Pasteur – Should be used within 24 hours of reconstitution if used alone or when reconstituted with Aventis Pasteur DTP. If Aventis Pasteur DTaP is used to reconstitute ACTHIB, the TriHibit vaccine must be used within 30 minutes. Only Aventis Pasteur DTP, DTaP, or the diluent shipped with the product, may be used to reconstitute the Aventis Pasteur ACTHIB product. Pedvax Hib- Merck- available in liquid one-dose vials good for 24 hours after reconstitution if kept at 2°-8°C (35°-46°F).

Appendix D

Hepatitis Vaccine: Hepatitis A and Hepatitis B

Shipping Requirements ***

Use insulated container. Must be shipped with refrigerant.

Condition on Arrival*

Should not have been **frozen**. Refrigerate on arrival.

Storage Requirements

Refrigerate immediately on arrival. Store at 2°-8°C (35°-46°F). **Do not freeze**.

Shelf Life

Up to 3 years. Check date on vial or container.

Instructions for Reconstitution or Use

Shake vial vigorously before withdrawing each dose.

Shelf Life after Reconstitution, or Opening

Until outdated, if not contaminated.

Special Instructions

Rotate stock so that the shortest dated material is used first.

HiB or HBCV: *Haemophilus Conjugate Vaccine*

Shipping Requirements

Should be shipped in insulated container to help prevent **freezing**.

Condition on Arrival*

Should not have been **frozen**. Refrigerate on arrival.

Storage Requirements

Refrigerate immediately on arrival. Store at 2°-8°C (35°-46°F). **Do not freeze** – this reduces potency.

Shelf Life

Up to 2 years. Check date on vial or container.

Instructions for Reconstitution or Use

Reconstitute before use. If the product requires reconstitution, record date of reconstitution on vial. Use only diluent supplied.

Shelf Life after Reconstitution, or Opening of Multidose Vials – Stable until date of expiration, if stored at 2°-8°C (35°-46°F) when not in use.

Single Dose Vials** – Discard unused reconstituted vials after 24 hours.

Special Instructions

Rotate stock so that the shortest dated material is used first.

* If you have questions about the condition of the material at the time of delivery, you should:

1) Immediately place material in recommended storage; and 2) Notify the Quality Control office of the vaccine manufacturer; or 3) Notify the National Immunization Program, CDC, Atlanta, Georgia.

** ACTHIB – Aventis Pasteur – Should be used within 24 hours of reconstitution if used alone or when reconstituted with Aventis Pasteur DTp. If Aventis Pasteur DTaP is used to reconstitute ACTHIB, the TriHibit vaccine must be used within 30 minutes. Only Aventis Pasteur DTp, DTaP or the diluent shipped with the product, may be used to reconstitute the Aventis Pasteur ACTHIB product. Pedvax Hib- Merck- available in liquid one-dose vials good for 24 hours after reconstitution if kept at 2°-8°C (35°-46°F).

***Engerix by Glaxo Smithkline may be shipped without refrigerant for up to 96 hours as long as the vaccine does not exceed 86°F.

Influenza Vaccine

Shipping Requirements

Should be delivered in the shortest possible time. Should not be exposed to excessive temperatures.

Condition on Arrival*

Should not have been **frozen**. Refrigerate on arrival.

Storage Requirements

Refrigerate immediately on arrival. Store at 2°-8°C (35°-46°F). **Do not freeze**.

Shelf Life

Formulated for use within current influenza season.

Instructions for Reconstitution or Use

Shake vial vigorously before withdrawing each dose.

Shelf Life after Reconstitution, or Opening

Until outdated, if not contaminated.

Special Instructions

Rotate stock so that the shortest dated vaccine is used first.

IPV: Poliovirus Vaccine - Inactivated

Shipping Requirements

Should be shipped in insulated container with refrigerant.

Condition on Arrival*

Should not have been **frozen**. Refrigerate on arrival.

Storage Requirements

Refrigerate immediately on arrival. Store at 2°-8°C (35°-46°F). **Do not freeze**.

Shelf Life

Up to 18 months. Check date on package.

Instructions for Reconstitution or Use

Ampoule - 1 dose: Tap the ampoule to ensure that the solution is in the lower portion rather than in the neck of the ampoule. With sterile

needle and syringe, withdraw the contents of the ampoule into syringe, holding the ampoule in such a way that the point of the needle is kept immersed throughout the withdrawal.

Vial - 10 dose: Withdraw 0.5 cc of vaccine into separate sterile needle and syringe for each immunization.

Shelf Life after Reconstitution, or Opening

Ampoule: Discard if not used immediately.

Vial: Until outdated if not contaminated.

Special Instructions

Rotate stock so that the shortest dated vaccine is used first. The vaccine should be perfectly clear. Any vaccine showing particulate matter, turbidity, or change of color should be discarded.

* If you have questions about the condition of the material at the time of delivery, you should:
1) Immediately place material in recommended storage; and 2) Notify the Quality Control office of the vaccine manufacturer; or 3) Notify the National Immunization Program, CDC, Atlanta, Georgia.

Lyme Vaccine

Shipping Requirements

Should be shipped in insulated containers with temperature monitors, via overnight courier. Vaccine can tolerate up to 4 days at room temperature (20°-25°C; 68°-77°F). Coolant packs should be used to ship if the product is to be shipped for a long trip or if there are extremes of ambient temperature expected during the shipping time.

Condition on Arrival*

Should not have been **frozen**. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 2°-8°C (35°-46°F). **Do not freeze.**

Shelf Life

Up to 24 months. Check date on vial or container.

Instructions for Use

Shake well before withdrawal and use. Discard any vaccine remaining in a single dose vial.

Special Instructions

Inject intra-muscularly in the deltoid region. Do not inject intravenously, intradermally, or subcutaneously.

* If you have questions about the condition of the material at the time of delivery, you should:

1) Immediately place material in recommended storage; and 2) Notify the Quality Control office of the vaccine manufacturer; or 3) Notify the National Immunization Program, CDC, Atlanta, Georgia.

Measles Virus Vaccine, Mumps Virus Vaccine, Rubella Virus Vaccine Measles/Mumps/Rubella-MMR Vaccine, Measles/Rubella-MR Vaccine

Shipping Requirements

Vaccine – Use insulated container. Must be shipped with refrigerant. Maintain at 10°C (50°F) or less. If shipped with dry ice, diluent must be shipped separately.

Diluent – May be shipped with vaccine but **do not freeze**.

Condition on Arrival*

Should be below 10°C (50°F). If above this temperature, see instructions (*) below. **Do not use warm vaccine**. Refrigerate on arrival.

Storage Requirements

Vaccine may be stored separately from diluent. Store as follows: Vaccine – refrigerate immediately on arrival. Store at 2°-8°C (35°-46°F). **Protect from light at all times**, since such exposure may inactivate the virus.

Diluent may be stored at 15°-30°C (59°-86°F) room temperature. **Do not Freeze**.

Special Note: Freeze dried (lyophilized) vaccines may be maintained at freezer temperatures.

Shelf Life

Vaccine – Up to 2 years. Check date on container or vial.

Diluent – Check date on container or vial.

Instructions for Reconstitution or Use

Reconstitute just before using. Use **only** the diluent **supplied** to reconstitute the vaccine.

Single Dose Vials – Inject diluent into the vial of lyophilized vaccine and agitate to ensure thorough mixing. Withdraw entire contents into syringe and inject total volume of vaccine subcutaneously.

Multidose Vials – Withdraw **all** diluent from vial into syringe. Inject into vial of lyophilized vaccine and agitate to ensure thorough mixing.

10-Dose Vials – Withdraw 0.5cc of reconstituted vaccine into separate sterile needle and syringe for each immunization. Licensed for jet injector use.

50-Dose Vials – Use on jet injector only, with dosage set at 0.5cc.

Shelf Life after Reconstitution, Thawing, or Opening

After reconstitution, use immediately or store in a dark place at 2°-8°C (35°-46°F). **Discard if not used within 8 hours**.

Special Instructions

Rotate stock so that the shortest dated vaccine is used first.

10-Dose Vials – May be used for both jet injector and needle and syringe methods of immunization.

50-Dose Vials – For jet injector use. Should not be utilized via needle and syringe method of immunization.

NOTE: All materials used for administering live virus vaccines should be burned, boiled, or autoclaved prior to disposal.

* If you have questions about the condition of the material at the time of delivery, you should:

1) Immediately place material in recommended storage; and 2) Notify the Quality Control office of the vaccine manufacturer; or 3) Notify the National Immunization Program, CDC, Atlanta, Georgia.

Appendix D

Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W-135

Shipping Requirements

Should be shipped in insulated containers with temperature monitors, via overnight courier. Powdered vaccine can tolerate up to 45° C (113° F) for 6-8 weeks. Coolant packs should be used to ship if the product is to be shipped for a long trip or if there are extremes of ambient temperature expected during the shipping time.

Condition on Arrival*

Should not have been **frozen**. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 2°- 8° C (35°- 46° F). **Do not freeze**. Powdered form can tolerate 12 weeks at 37° C (98.6° F) and 6 to 8 weeks at 45° C (113° F).

Shelf Life

Expires within 18 months. Check date on vial or container.

Instructions for Reconstitution and Use

Reconstitute gently. This is a white powder that yields a clear colorless liquid when reconstituted with 0.5 ml of sterile water.

Shelf Life after Reconstitution or Opening

Use single dose vials within 24 hours of reconstitution. Unused portions of multi-dose vials may be refrigerated at 2°- 8° C (35°- 46° F) and used up to 10 days after reconstitution.

Special Instructions

Diluent to be used is sterile water for injection with 0.01% thimerosal. Reconstituted vaccine should be injected subcutaneously, or with a jet injector device only. Do not inject intra-dermally, intramuscularly, or intravenously.

Pneumococcal 7-valent Conjugate Vaccine

Shipping Requirements

Should be shipped in insulated containers at 2°- 8° C (35°- 46° F) with temperature monitors.

Condition on Arrival*

Should not have been **frozen**. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 2°-8°C (35°-46°F) **Do not freeze**.

Instructions for Reconstitution and Use

Vaccine should appear as a homogenous white suspension after vigorous shaking. The vaccine should be administered intramuscularly only.

Special Instructions

This vaccine is a suspension containing adjuvant and, if after vigorous shaking, should not be used if the particles can not be resuspended.

Shelf Life

Up to 18 months. Check date on vial or container.

* If you have questions about the condition of the material at the time of delivery, you should:
1) Immediately place material in recommended storage; and 2) Notify the Quality Control office of the vaccine manufacturer; or 3) Notify the National Immunization Program, CDC, Atlanta, Georgia.

Pneumococcal Polysaccharide Vaccine — Polyvalent

Shipping Requirements

Should be shipped in insulated container with refrigerant. **Do not freeze.**

Condition on Arrival*

Should not have been frozen. Refrigerate on arrival.

Storage Requirements

Refrigerate immediately on arrival. Store at 2°-8°C (35°-46°F). **Do not freeze.**

Shelf Life

Up to 2 years. Check date on container or vial.

Instructions for Reconstitution or Use

Vials — Shake vial vigorously before withdrawing each dose.

Prefilled Syringes — Follow manufacturer's directions.

Shelf Life after Reconstitution, or Opening

Until outdated, if not contaminated.

Special Instructions

Rotate stock so that the shortest dated vaccine is used first. **Do not inject intravenously.** Intra-dermal administration may cause severe local reactions and should be avoided.

Td—Adult: Tetanus-Diphtheria Toxoids DT—Pediatric: Diphtheria-Tetanus Toxoids

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 2°-8°C (35°-46°F). **Do not freeze** or store vaccine in direct contact with refrigerant.

Condition on Arrival*

Should not have been **frozen**. Refrigerate on arrival.

Storage Requirements

Refrigerate immediately on arrival. Store at 2°-8°C (35°-46°F). **Do not freeze.**

Shelf Life

Up to 2 years. Check date on vial or container.

Instructions for Reconstitution or Use

Shake vial vigorously before withdrawing each dose.

Shelf Life after Reconstitution, Thawing, or Opening

Until outdated, if not contaminated.

Special Instructions

Rotate stock so that the shortest dated vaccine is used first.

* If you have questions about the condition of the material at the time of delivery, you should:

1) Immediately place material in recommended storage; and 2) Notify the Quality Control office of the vaccine manufacturer; or 3) Notify the National Immunization Program, CDC, Atlanta, Georgia.

Varicella (Chickenpox) Vaccine

Shipping Requirements

Ship with dry ice only. Should be delivered within 2 days.

monitoring of the refrigerator temperature to avoid freezing killed or inactivated vaccines will be necessary.

Conditions on Arrival*

Should be frozen. Vaccine should remain at -20°C (-5°F) until arrival at health care facility. Dry ice should still be present in the shipping container when vaccine is delivered. See footnote below.

Shelf Life

Up to 18 months. Check date on package and use the earliest expiration date first.

Storage Requirements

Maintain in a continuously frozen state at -15°C (5°F) or colder. **No freeze thaw cycles are allowed with this vaccine.** Vaccine should only be stored in freezers or refrigerator/freezers with separate doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers with a separate, sealed freezer compartment. In order to maintain this temperature it will be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful

Instructions for Reconstitution or Use

This product is a lyophilized (freeze dried) product and should only be reconstituted with the diluent provided with the vaccine. This vaccine must be used within 30 minutes of reconstitution or should be discarded.

Special Instructions

If this vaccine is stored at a temperature warmer than -15°C, it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended storage, the health care provider should contact Merck, the manufacturer, at 1-800-9-827-4829 for a re-evaluation of the products potency before using the vaccine.

* If you have questions about the condition of the material at the time of delivery, you should:
1) Immediately place material in recommended storage; and 2) Notify the Quality Control office of the vaccine manufacturer; or 3) Notify the National Immunization Program, CDC, Atlanta, Georgia.